

REMARKS

Claims 1-30, 41-45, 48, 50-53, 55 and 56 are currently pending in the application. Claims 1-30, 43 and 44 have been withdrawn pursuant to the Office's Restriction Requirement. Claims 31-40, 46, 49, 54 and 57-59 have previously been canceled. Claims 41 and 45 have been amended as discussed below without prejudice to, or disclaimer of, the subject matter thereof. Claims 47, 50 and 51 have been amended to correct typographical errors or adjust claim dependency based on claim cancellation. These amendments are also made without prejudice to, or disclaimer of, the subject matter thereof. Applicants reserve the right to file divisional or continuing applications directed to the subject matter of any claim withdrawn, canceled or amended for any reason.

It is submitted that no new matter has been introduced by the amendments with support found throughout the specification as filed. By the amendments, Applicants do not acquiesce to the propriety of the Office's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 USPQ.2d 1865 (US 1997).

Applicants thank the Office for the courtesy of a telephone conference to discuss this Office Action, on October 19, 2009.

I. Claim Objections

The Office Action states that the previous objections to the claims have been withdrawn. Office Action mailed August 5, 2009 ("OA"), page 2. Applicants thank the Office for withdrawing these objections.

II. Claim Rejections

A. 35 U.S.C. § 112, first paragraph

Claims 41, 42, 45, 47, 48, 50-53, 55 and 56 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly containing new matter. OA, page 2. Applicants respectfully disagree.

According to the Office, the amendment to recite inflammation due to IL-8 or GRO- α raises a new matter issue, because the specification has no description of what these inflammations are. OA, page 2. The claimed methods relate to an early stage in inflammation that is mediated by chemokines including IL-8 and GRO- α . Paragraph 0005 of the pending specification (U.S. Publication No. 20050026965) states,

...Chemokines are typically low-molecular-mass (7-9 kd) proteins that can be divided into four subfamilies ... and are categorized by their primary amino acid structure. The CXC subfamily is characterized by the two conserved Cys residues (C) near the N-terminus and separated by an amino acid (X). Some of the CXC chemokines, of which IL-8 and GRO- α are representative, belong further to the ELR+ subfamily (Glu-Leu-Arg) and are important in the recruitment and activation of neutrophils via the CXCR1 and CXCR2 receptors.

The next several paragraphs of the specification give examples of inflammatory conditions that relate to this recruitment and activation of neutrophils. These include sepsis (paragraph 0008); rheumatoid arthritis and synovitis (paragraph 0009); atherosclerosis (paragraph 0010); and colitis and psoriasis (paragraph 0012). Thus, the application does disclose examples of a broad range of inflammatory conditions in which recruitment and activation of neutrophils via the CXC receptors plays a role. The application also discloses a role generally for CXC receptors in neutrophil chemotaxis in inflammation:

[0008] The role, in inflammatory disorders, of neutrophil chemotaxis mediated by the CXCR1 and CXCR2 receptors is generally accepted.

Based on the foregoing, Applicants respectfully request that the Office reconsider and withdraw the rejection of claims 41, 42, 45, 47, 48, 50-53, 55 and 56 under 35 U.S.C. § 112, first paragraph based on new matter. If the Office does not withdraw these rejections, Applicants respectfully remind the Office that under the principles of compact prosecution, the Office should look for allowable subject matter and communicate to Applicants what that subject matter is at the earliest point possible in the prosecution of the application. MPEP § 2164.04.

B. Obviousness-Type Double Patenting

Claims 41, 42, 45, 47, 48, 50-53, 55 and 56 stand rejected on the ground of nonstatutory obviousness-type double patenting over claims 48 and 49 of U.S. Patent No. 6,777,432. OA, page 3. The Office states that the claims are not patently distinct because claims 48 and 49 are also drawn to the method of treating inflammatory disorders alleviated by inhibition of GRO. Applicants respectfully disagree.

The 6,777,432 patent does not disclose compounds having the N-oxide structure, so the methods of claims 48 and 49 of that patent do not include the use of N-oxide compounds as claimed in the present application (see declaration of inventor, Neil Cutshall).

Claims 41, 42, 45, 47, 48, 50-53, 55 and 56 stand rejected on the ground of nonstatutory obviousness-type double patenting over claims 1 and 2 of U.S. Patent No. 7,151,112. OA, page 3. The Office states that the claims are not patently distinct because claims 1 and 2 are also drawn to the method of inhibiting IL-8 and GRO and mediating the associated disorders. OA, pages 3-4. Applicants respectfully disagree.

The 7,151,112 patent does not disclose compounds having the N-oxide structure, so the methods of claims 1 and 2 of that patent do not include the use of N-oxide compounds as claimed in the present application (see declaration of inventor, Neil Cutshall).

Accordingly, Applicants respectfully request that the Office reconsider and withdraw the obviousness-type double patenting rejections over U.S. Patent Nos. 6,777,432 and 7,151,112.

C. 35 U.S.C. § 102

Claims 41, 42, 45, 47, 48, 50-53, 55 and 56 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kibanov, B.N. *et al.* OA, page 4. According to the Office, the reference reads on the compounds when R1 is R5 and R5 is H. OA, page 5. Without acquiescing to this ground of rejection, claims 41 and 45 have been amended, and Applicants submit that the claims as amended are not anticipated by the reference.

Accordingly, Applicants respectfully request that the Office reconsider and withdraw the pending rejections of claims 41, 42, 45, 47, 48, 50-53, 55 and 56 under 35 U.S.C. § 102(b).

D. 35 U.S.C. § 112

Claims 41, 42, 45, 47, 48, 50-53, 55 and 56 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. OA, page 6. Applicants respectfully disagree.

According to the Office, there is no description of what is included in the term “mediated at least in part by IL-8 and GRO- α .” Applicants bring to the Office’s attention to paragraph 0100, which states in part,

[t]he present invention provides nicotinanilide N-oxide, compositions containing a nicotinanilide N-oxide, and methods of using nicotinanilide N-oxide compounds to inhibit chemokine-mediated cellular events involving IL-8, including IL-8a (CXCR1 receptor) and IL-8b (CXCR2 receptor).

Applicants have amended claim 41 to better track the specific language of the specification, although Applicants do not concur that the prior language was not compliant with the written description requirement. This amendment also remedies the rejection of claim 42, which depends from claim 41. The objectionable language does not appear in claim 45 or the claims depending therefrom, so Applicants submit that the rejection is moot in relation to claims 45, 47, 48, 50-53, 55 and 56.

Accordingly, Applicants respectfully request that the Office reconsider and withdraw the pending rejections of claims 41, 42, 45, 47, 48, 50-53, 55 and 56 under 35 U.S.C. §112, first paragraph.

CONCLUSION

Applicants have properly and fully addressed each of the Office's grounds for rejection. Applicants submit that the present application is now in condition for allowance. If the Office has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited. If there are any additional fees due in connection with the filing of this amendment, please charge the fees to K&L Gates Deposit Account No. 50-3207. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account.

Respectfully Submitted,

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/C. Rachal Winger/

C. Rachal Winger, Ph.D.

Registration No. 55,815

CUSTOMER NUMBER: 85,943

K&L GATES LLP

925 Fourth Avenue, Suite 2900

Seattle, WA 98104

Telephone: (206) 370-6641

Email: seattle.patents@klgates.com